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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,876	06/28/2000	Mercy M. Davidson	0575/56614/JPW/JML/HA	6365

7590 01/25/2005

Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/604,876	DAVIDSON, MERCY M.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,8,9 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3-5,8,9 and 12* is/are allowed.

6)☐ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/04 has been entered.

Claims 13-19 were canceled as requested.

Claims 1, 3-5, 8, 9, and 12 remain pending in the application and are under consideration in this Office Action.

An information disclosure statement was received with the request for continued examination. An initialed and signed copy indicating consideration of the references is attached.

Objections Withdrawn

The objection to claims 3-5 is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (In Vitro Cellular and Developmental Biology 27(1): 63-74, 1/1991).

Claim 1 is a product-by-process claim drawn to an immortalized human undifferentiated cardiomyocyte cell line produced by a particular process. The process requires fusing a post-mitotic primary non-immortalized human cardiomyocyte obtained from adult human heart tissue, wherein the cardiomyocyte has fused with a human fibroblast that has been treated with ethidium bromide, lacks mitochondrial DNA, and comprises a replicable vector expressing SV40 large T antigen. The claim requires that the cell line must express SV-40 large T-antigen.

MPEP 2113 states that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by these steps. The only clear structural requirements of the instantly claimed product are that it comprises a replicable vector expressing SV40 large T antigen, it contains no fibroblast mitochondrial DNA. The functional limitation "immortalized" is clear of one to skill in the art and breaths life and meaning in to the claim. In contrast, the preamble phrase "undifferentiated cardiomyocyte" carries little weight. The term "cardiomyocyte" by itself might imply certain structural and functional characteristics that would breath life and meaning into the claim, however it is unclear what are the minimum requirements that must be met for a cell to be considered an "undifferentiated" cardiomyocyte. For example, it is unclear what markers would need to be expressed, and what physiological characteristics would have to be apparent. So, "undifferentiated cardiomyocyte" is given little weight. Also, the structural and functional consequences

of fusion with a fibroblast are unclear, other than that the claimed product must comprise a replicable vector that expresses SV-40 large T antigen. As such, the claimed cell line would be anticipated by any immortalized human cell line comprising a replicable vector that expresses SV-40 large T antigen.

Wang taught a human fetal cardiac myocyte cell line designated W1 that carries an expression vector encoding SV40 T antigen (pRSVTAg). See abstract and page 67, column 2, last complete sentence. This line is considered to be immortalized because it was maintained in culture for one year. See abstract. This immortalization is considered by Wang to be evidence that the cells express T antigen. Wang taught that the pRSVTAg vector appeared to be integrated into cellular chromosomal DNA. See page 73, column 1, lines 5-11. This ensures that the vector is replicable.

The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989). In this case the cell line of Wang possesses the only clearly delineated structural feature of the claimed cell line. Thus Wang anticipates the claim.

Response to Arguments

Applicant's arguments filed 11/12/04 have been fully considered but they are not persuasive. Applicant argues that the W1 cell line of Wang is not the same as the claimed cell line, because it is derived from a fetal cardiomyocyte, and not from an adult cell line. This is unpersuasive because it is unclear that derivation from a fetal cardiomyocyte would lead to a structurally and functionally different cell than that which is claimed. As stated above, the claim is a product by process claim wherein there are only three clear structural and functional limitations: the cell line must be immortalized, undifferentiated, and must comprise a replicable expression vector that expresses SV40 large T antigen. The cell line of Wang meets these limitations, so Wang fairly anticipates the claim. In addition, the specification teaches at page 19, lines 38-40 that the cells obtained by the recited method steps had the same growth properties regardless of whether they originated from fetal or adult cardiomyocytes. Thus the available evidence suggests that immortalized undifferentiated human cardiomyocyte cell lines derived from fetal cardiomyocytes are indistinguishable from those derived from adult cells.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is a product-by-process claim drawn to an immortalized human undifferentiated cardiomyocyte cell line produced by a particular process. The process requires fusing a post-mitotic primary non-immortalized human cardiomyocyte obtained from adult human heart tissue, wherein the cardiomyocyte has fused with a human fibroblast that has been treated with ethidium bromide, lacks mitochondrial DNA, and comprises a replicable vector expressing SV40 large T antigen. The claim requires that the cell line must express SV-40 large T-antigen.

This process could lead to the generation of a large variety of cell types depending on the outcome of the fusion process, i.e. depending on how many copies of various chromosomes the resulting heterokaryons received; depending on the genotypes of the contributing fibroblast and cardiomyocyte; and depending on the relative contributions from the parent cells of cytoplasmic and nuclear factors that affect gene expression, and cell morphology, structure, and function. So, the claim as written is interpreted as embracing a broad genus of cells with different structural and functional characteristics. As noted above, the limitation "undifferentiated cardiomyocyte" receives very little patentable weight because it is unclear what structural and functional characteristics an undifferentiated cell must have in order to be considered an

undifferentiated cardiomyocyte. More particularly, it is unclear how an undifferentiated cardiomyocyte differs from any other undifferentiated cell.

Based on the specification from page 19, line 25 to page 20, line 6, five undifferentiated cell lines were produced that expressed SV40 large T antigen, beta myosin heavy chain, desmin, and connexin-43. These last three proteins are known to be expressed in cardiac muscle. Thus the specification discloses a representative number of species of the subgenus of immortalized undifferentiated cardiomyocyte cell lines that express SV40 large T antigen, beta myosin heavy chain, desmin, and connexin-43. The specification discloses no other types of cell line representative of the broad genus of possible outcomes of the recited method steps. It is suggested that the claim should be limited to an of immortalized undifferentiated cardiomyocyte cell line that expresses SV40 large T antigen, beta myosin heavy chain, desmin, and connexin-43.

Conclusion

Claims 3-5, 8, 9, and 12 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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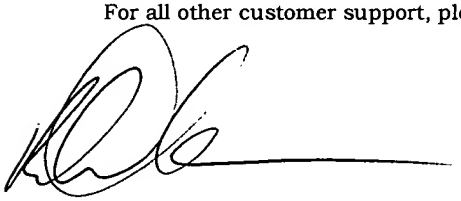

Richard Schnizer, Ph.D.